Endologix Announces Limited Recall of Catheter

Medicis, Inamed end merger agreement; Siemens partners with EMC; St. Jude Acquires Savacor

Irvine, CA-based Endologix, Inc., manufacturer of minimally invasive treatments for vascular diseases, notified the FDA that it is voluntarily recalling selected Powerlink System delivery catheters marketed in the United States. The recall comes as a result of three recent reports of tip separation from the catheter sheath's inner core during procedures.

"I am confident our regulatory and quality team, working closely with the FDA, and our marketing and field personnel will effectively complete this action involving an estimated 35 catheters in an organized and efficient manner," said Paul McCormick, president and CEO of Endologix.

However, company officials noted that the recall does not affect the Powerlink stent grafts that have been implanted in patients, nor does it include the large-diameter 34-mm Powerlink System or Powerlink systems sold outside the United States.

Endologix has determined the action to be a Class 2 recall, although final determination is pending FDA review.

FDA Requests Data for Injection Device

The FDA requested additional information about an ongoing study of a needle-free drug injection system from Swiss drug maker Roche Holding Ltd. and Trimeris, Inc., a Morrisville, NC-based biotech firm. The request for information was reportedly the result of the companies' request to have the FDA include information on the device in labeling for Fuzeon, an HIV drug.

The Biojector 2000, manufactured by Bedminster, NJ-based Bioject Medical Technologies, Inc., is designed to administer Fuzeon, an HIV blocker that was jointly developed by Roche and Trimeris. The Biojector uses a carbon-powered injector to disperse liquid medication underneath the skin without the use of needles.

Medicis, Inamed End Merger Agreement

Scottsdale, AZ-based Medicis, manufacturer of specialty pharmaceuticals for dermatologic and podiatric conditions, terminated its merger agreement with Santa Barbara, CA-based Inamed Corporation. Inamed, maker of breast implants and dermal products, originally entered into a $2.8 billion stock and cash merger agreement with Medicis in March 2005.

The decision to forego the merger was reportedly the result of Inamed's refusal to reject a competing $3.2 billion cash and stock bid from Irvine, CA-based Allergan last December.

"After careful evaluation by the Board of Directors, with consultation from outside counsel and financial advisors, we have concluded that it is in the best interests of Medicis shareholders not to raise our offer for Inamed," said Jonah Shacknai, chairman and CEO of Medicis.

Subsequently, Allergan, Inc., a developer of specialty dermatology products, has proceeded to accept a merger agreement with Inamed and is currently awaiting SEC approval. Inamed, however, reportedly will not sign the agreement until Allergan is satisfied with results of an investigation conducted by Inamed into its wrinkle-smoother, Juvederm.

The Allergan-Inamed merger could force stand-alone Medicis to re-evaluate a $2.2 billion stock offer it refused in November from Mentor Corporation, which manufactures breast implants. As part of the termination between Medicis and Inamed, Medicis will receive a $90 million termination fee from Inamed.

Point Technologies Acquired by AMIH

Boulder, CO-based Point Technologies, Inc. was acquired by American Medical

Collaborations & Alliances

ITC Signs Distribution Agreement With Surgilance, Inc.

International Technidyne Corporation (ITC) of Edison, NJ, maker of Tenderfoot, a device for painlessly obtaining blood samples from infants' heels, has announced that Norcross, GA-based Surgilance, Inc. will become its semi-exclusive distributor is the US hospital market and a nonexclusive distributor in the alternate site market.

"Surgilance's strong market coverage in the hospital sector will help ITC continue to grow Tenderfoot in the US market," said ITC President Lawrence Cohen.

Focusing on major group purchasing organizations and integrated distribution networks, Surgilance, Inc., whose Safety Lancet is one of the top four selling lancets in the country, plans on using its direct sales force and telesales organization to market the line of finger stick devices along with ITC's Tenderfoot.

Siemens Medical Partners With EMC Corp.

Malvern, PA-based Siemens Medical Solutions, maker of medical imaging equipment, has announced a strategic alliance with Hopkinton, MA-based information management provider EMC Corp. The synergy will allow healthcare providers to store, manage and protect patient information more efficiently while allowing clinicians to focus more on patient care.

"EMC's world-class storage and information management expertise, combined with Siemens' comprehensive portfolio of medical imaging and information technologies, enables us to deliver complete solutions that bring exceptional value to our customers," said Gordon Rice, senior vice president, Customer Solutions Group of Siemens Medical Solutions.

As patient information becomes more digitized and image volumes increase, healthcare providers continually look for solutions to help them optimize their information infrastructure and improve clinical productivity. The Siemens and EMC alliance will enable Siemens to bring a full range of EMC storage systems to the healthcare market.

Integrated BioSciences Signs MOUs With Unilife Medical

Integrated BioSciences, Inc. (IBS), contract manufacturer of medical devices, has signed two Memorandums of Understanding (MOU) with Unilife Medical Solutions, an Australian company that develops and commercializes healthcare safety products.

In adherence to the first MOU, IBS will build an automated assembly line for the Unitract Clinical line of safety syringes, and will also make IBS the sole US manufacturer of the product. Assisting in the design and development of the line is West Pharmaceuticals of Lionville, PA.



According to the second MOU, IBS will create a North America production center for the 1 mL Unitract Safe Syringe at its headquarters in Lewisbury, PA. Unilife has reportedly receivedorders for 30 million units of the 1 mL Safe Syringe from the United Kingdom and China, and IBS will be the exclusive North American manufacturer for these markets as well as future global markets.

Production of the Unitract Safe Syringe as well as the Unitract Clinical line of products is slated to begin in the fourth quarter of 2006, pending completion of the assembly line.

Instruments Holdings Inc. (AMIH) in a stock purchase deal, the companies announced. The global component manufacturing company, which serves the biotech, medical device, and semiconductor industries, will become the contract manufacturing division of AMIH serving OEMs.

While financial details were not disclosed, Point Technologies will assume the resources of AMIH's existing Inter-V OEM division, which includes Manan Medical Products, Medical Device Technologies and American Medical Instruments. Manufacturing sites for the new division will be located in Boulder, CO; Gibbon, MN; Wheeling, IL; Gainesville, FL; Dartmouth, MA; and Heredia, Costa Rica.

Plans are under way to enlarge the existing Technology Center and enhance service offerings, which presently include prototype design, advanced micromachining processes and assembly and final packaging. Point Technologies completes manufacturing of components by using preci-

sion wire and tube micro-machining, burr-free cutting and electrochemical pointing and plating technologies for small diameter wire and tubing.

The acquisition will afford the company an opportunity to add other capabilities to the list, including device assembly, plastic injection molding, wire and tube grinding, laser welding, NiTi heat setting and final packaging, among others.

The new AMIH division will be overseen by Kirk O'Brien, who was the principal owner of Point Technologies and now will serve as president of this division, which will provide incision technology as well as precision wire and tube machining for endoscopic, ophthalmic, arthroscopic, orthopedic, ENT and other minimally invasive applications.

Mexico's President Visits Moll Mexico

Plastic injection molder and contract manufacturer Moll Mexico received a visit from Mexico's President Vicente Fox at the company's newly constructed plant in Ramos Arizpe, Coahulla. On hand at the ceremony was Governor Martinez y Martinez, who was accompanied by Ernest Saro, mayor of Ramos Arizpe.

Fox expressed his gratitude for the company's investment into Mexico and its dedication to building state-of-the-art facilities that adhere to strict standards of efficiency and quality. Fox also acknowledged the importance of a joint US-Latin American collaboration in the face of stiff Asian and global manufacturing competition.

With full-scale operations scheduled to commence in February 2006, the plant will utilize approximately 35 presses, with space available for up to as many as 50, and will concentrate on molding, secondary processing and assembly for the appliance, automotive, medical and electronics industries.

The Ramos plant is the third site for Moll Mexico, a Mexican company owned by Moll Holdings, a US entity that also owns Moll Industries, Inc. The new plant is expected to extend the capabilities and current production of Moll's facilities in Monterry and Empalme, Sonora.

Moll's core technologies include two-shot gas-assist insert molding, in and over mold decoration as well as postmold decoration.

TexLoc and TexMed Join Parker Hannifin

With annual sales exceeding $8 billion, Fort Worth, TX-based Parker Hannifin Corporation, a manufacturer of motion and control technologies, has acquired TexLoc Ltd. and its medical division, TexMed, designer and manufacturer of fluoroplastic tubing products. The cash sum was not disclosed.

"Parker will provide a great opportunity for TexLoc and TexMed to expand our products globally. [It's] global presence and reputation for quality will enable wider distribution of the products we are proud to have developed," said Dan Rodriguez, general manager of TexLoc.

Parker employs 50,000+ people in 48 countries. The company holds one of the top five longest-running dividend-increase records in Standard & Poor's 500 index.

Vaupell Opens New Facility in Agawam

Seattle, WA-based Vaupell has put the finishing touches on its new 105,000 square-foot manufacturing facility in Agawam, MA. The new plant is home to Vaupell New England Molding & Tooling and Vaupell Precision Machining.

Features include 11,500 square feet of Class 7 and Class 8 clean room area; 23,000 square feet for precision machining, tool making and gauging; 57,000 square feet for injection molding; and 15,000 square feet for assembly. Vaupell is ISO 9001:2000 certified and plans to be DIN-ISO 13485:2003 certified by mid-2006.

Round Rock Creates Circuits With Jabil

With a dramatic increase in sales for LCD and plasma displays, St. Petersburg, FL-based Jabil Circuit, Inc. has acquired the Round Rock, TX operations of Incline Global Technology Services, Inc., which deals with LCD and plasma display panels repair services.

"The acquisition of Incline will expand our already robust technical capabilities in LCD and plasma design, manufacturing and repair, as well as increase our ability to serve all our customers in this specialized field," stated Harmut Liebel, president of Jabil Global Services.

As the demand for consumer and business LCD and plasma display grows, so does the need for repair services. Round Rock's Texas plant is capable of repairing 20,000 to 25,000 LCD panels per month, and by transferring Incline's technology and experience to Jabil's facilities throughout the Americas, Europe and Asia, Jabil reported it expects Round Rock to be the LCD Center of Excellence for repair services.

"Our extensive capability in LCD and plasma technology, combined with our global hub service strategy, enables Jabil to provide a uniquely rapid, reliable, and low-cost repair turn-around—a very compelling value to our customers," Liebel said.

With an employee roster of 45,000 and facilities in 19 countries, Jabil provides comprehensive electronics design, manufacturing and product management services to global electronics and technology companies worldwide.

Hi-Tech Group Forms Technology Task Force

With the recent merger of Hi-Tech Rubber, A.C. Hoffman Engineering and Inland Technologies, the parent company, Hi-Tech Group (HTG), has created a Technology Task Force to ensure its customers' products are manufactured using the most advanced equipment and quality assurances available.

Originally the brainchild of HTG's Chairman, Neil Martin, the Technology Task Force is charged with researching and assessing the latest technologies and then adapting them to enhance HTG's manufacturing capabilities and better meet customer needs.

The Task Force is comprised of Tom Jenkins and Steve Herman from A.C. Hoffman Engineering; Ray Shapland, Phil Benker and Rey Obnamia from Hi-Tech Rubber; and Gary Hengeveld, Larry Espinosa and Tom Diaz from Inland Technologies. Company officials said each member represents some the most experienced rubber and plastic specialists in their respective fields, including tool design,

process engineering, manufacturing, material formulation, operational systems and product quality assurance.

"As a manufacturer, the only way to compete in a highly competitive marketplace is to consistently deliver the highest quality products and services in the shortest period of time and in the most cost-effective manner," said Jenkins of Hoffman Engineering. "That is why it is important to invest in the development and implementation of the latest technology available today. That is the only way to ensure that our customers stay on the leading edge."

Tom Diaz, tooling and engineering manager for Inland Technologies, said "the merger of different disciplines—plastic, rubber and silicone—allows us to access all of our resources in one company; gives us more exposure to new technologies, parts and ideas; and provides a wider array of solutions for our customers. It's very exciting."

Based in Anaheim, CA, HTG manufactures tight-tolerance rubber and plastic components primarily for the medical device field.

Expansion Puts IncisionTech on the Cutting Edge

Precision cutting and piercing component manufacturer IncisionTech plans a $6 million expansion for its Staunton, VA facility with the addition of 28,000 square feet to its current campus. The expansion will create 25 new jobs and augment the company's product offering with new precision grinding and Yag-based laser equipment.

Established this past summer as a separate division of parent company Specialty Blades, Inc., IncisionTech focuses exclusively on OEM medical device applications.

Patients worldwide will also benefit from the company's product line with the opening of a Shanghai, China sales office to address the developing Chinese market.

Accumold Begins Plant Expansion

Accumold Corp. has acquired new thermoplastic molding machines as part of a major expansion to accommodate rapid growth in its micromolding business.

The Ankeny, IA-based company has entered into the first phase of its expansion in response to a significant increase in component manufacturing once performed by companies in China, India and Thailand.

"Our customers have found that we can deliver consistently higher quality components faster and at a cost that is very competitive with overseas manufacturers," said Roger Hargens, CEO and president of Accumold.

The company also expects to break ground in late 2006 for an expansion of its 38,000 square-foot plant and to acquire additional land for future development.

St. Jude Acquires Cardiac Specialty Company

St. Paul, MN-based St. Jude Medical announced its agreement to acquire Los Angeles, CA-based Savacor for $50 million.

St. Jude Medical, a medical device manufacturer, reportedly made this move in an attempt to capitalize on Savacor's cardiac capabilities. Savacor currently has various diagnostic and therapeutic technologies under development and in clinical evaluation for use in heart failure. In addition, clinical trials are under way for Savacor's implantable sensor device that measures left atrial pressure and body temperature.

"The Savacor technology has exciting potential and will complement the development efforts already under way at St. Jude Medical in managing the comorbidities of heart failure patients," said Michael J. Coyle, president of St. Jude Medical's Cardiac Rhythm Management business. "We are pleased to welcome the Savacor team to St. Jude Medical."

MPO Summit to Address Strategic Manufacturing Issues for Medical OEMs With Educational Conference & Exhibition

Medical Product Outsourcing will hold its next MPO Summit April 16-19 in San Francisco, CA. This exciting event follows its successful launch event in 2005, when more than 150 industry executives met in Princeton, NJ.

The West Coast sequel will cover topics such as evaluating the China market, assessing the regulatory environment and determining overall strategic plans for medical device manufacturers.

The mission of these events is to educate the industry and provide powerful networking opportunities for decision-makers. The conference is formatted to give participants a forum where they can discuss industry trends and to solve critical problems.

Representatives from major medical device manufacturing companies such as Johnson & Johnson, Abbott Laboratories, Baxter Healthcare, Boston Scientific and Lilly have participated in the past as speakers and attendees.

In addition to the Bay Area event, MPO will host an East Coast Summit September 25-27 in East Rutherford, NJ. Future events will maintain a high quality of educational content and offer access to a select group of contract manufacturers and suppliers exhibiting on-site.

Early supporters of the event include Norman Noble, Inc. (an Elite Partner), Avail (Platinum), B. Braun and Memry Corporation (both Gold Partners). Medical Design Technology magazine is serving as Media Partner, and the Medical Device Manufacturers Association is a key endorser.

"We are here to advocate growth and development of the industry," said Howard Revitch, publisher of *Medical Product Outsourcing* magazine. "The industry has a lot of conferences and trade shows, but the MPO Summit differentiates itself by staying focused on the importance of collaborating to improve medical device manufacturing on the whole. We are dedicated to doing that."

For more information on speaker, sponsorship and exhibition opportunities, please e-mail info@mposummit.com, visit www.mposummit.com, or call Howard Revitch at 201-825-2552 x343.

3M to Acquire Siemens Circuitry

An agreement has been reached for 3M, based in Saint Paul, MN, to acquire Siemens Ultrasound Division's flexible circuit manufacturing line in Canoga Park, CA.

"We see strong technical synergies with 3M," said Bob Froehlich, director of operations at Siemens' Canoga Park location. "Together we will expand the businesses beyond the current customer base."

The Siemens division acquisition, which, at press time, was reported to close by the end of 2005, is expected to expand 3M's business in the ultrasound market, according to Frank R. Little, division vice president for 3M Electronic Solutions Division.

The Siemens Ultrasound Division produces flexible interconnect circuits providing electrical connections between components in electronic systems, such as transducers of ultrasound machines. 3M Electronics already offers flex circuits used in medical devices and diagnostics, among other applications.

The Siemens Ultrasound Division, which has 56 employees, will remain in its present location, company officials reported.

PhotoMedex Settles With Edwards

Medical device manufacturer PhotoMedex of Montgomeryville, PA said it has settled the company's lawsuit against Irvine, CA-based Edwards Lifesciences Corp. and Baxter Healthcare Corp. of Deerfield, IL.

According to a lawsuit filed by PhotoMedex in January 2004, Edwards—and Baxter, Edward's former parent corporation—breached agreements to develop and commercialize PhotoMedex's patented Excimer laser technology used in transmyocardial revascularization. The lawsuit also alleged that Edwards improperly granted certain rights to a competitor regarding the technology that PhotoMedex had acquired "at Baxter's insistence for $4 million."

The lawsuit was seeking the return of the $4 million plus costs and interest; however, the terms of the settlement were not disclosed.

PhotoMedex President and CEO Jeffrey F. O'Donnell said, "While certain details of the settlement are subject to confidentiality restrictions, we can say that the settlement provides some working capital to the company that will be useful for our domestic marketing program for the XTrac Excimer laser."

Dade Behring Opens European Distribution Center

Deerfield, IL-based Dade Behring Inc., a maker of clinical diagnostics, announced the opening of a new distribution center in Duisburg, Germany.

Located at Logport, a logistic service center managed by the German Duisport-Group, this new center will offer efficient transporting of products by sea, air, railway and roadways.

"All of the advantages that the Duisburg location offers, including the high-technology logistic center and the excellent port access to rail transport, give us confidence that we have made the right choice for the placement of a successful distribution center," said Carsten Taucke, managing director Marburg, Dade Behring.

Features of the facility include an advanced robotic system and newer technology to help ensure faster turnaround times for fulfillment of customer orders. In addition, this location offers Dade Behring room for expansion.

Dade Behring, which had $1.6 billion in revenues in 2004, ships approximately 465,000 packages yearly to 40 countries. The company's new center will store and distribute products for US and European customers, who can receive products in as little as 24 hours after placing orders.

"This new distribution center is an example of our consistent commitment to improving the service we provide our customers," said Jim Reid-Anderson, chairman, president and CEO of Dade Behring.

IDEO to Design Blood Coagulation Monitor

On the heels of its design for the INRatio monitor, IDEO has been selected by HemoSense, Inc. to design the next-generation INRatio PT/INR monitor that manages warfarin medication.

IDEO, a 400-personnel global design consultancy headquartered in Palo Alto, CA, had previously designed the current model of the INRatio monitor, which features a simple design, integrated quality control tests, ease of use and accurate results from a single blood drop.

San Jose, CA-based HemoSense, a maker of handheld blood coagulation systems for monitoring patients taking warfarin, was pleased with the success of its current INRatio product and believed IDEO's familiarity with the technology made the company a natural choice for designing the next-generation equipment.

Maria Navarro, executive vice president, operations, research and development for HemoSense, noted that IDEO's "commitment to technical innovation and user sensitivity made them a natural choice as we determine the feature set and user requirements of the new monitor."

IDEO Senior Project Manager and Manufacturing Specialist David Littleton added, "We are very pleased to have the opportunity to reunite with HemoSense to improve upon an already well-received product."

The INRatio system is used by both healthcare providers and patients to measure blood clotting time. The system, which is sold in the United States and internationally, consists of a small portable monitor and disposable test strips. ❖

Correction

In the November/December 2005 issue of *Medical Product Outsourcing*, we incorrectly identified Avail's headquarters as being located in State College, PA. The company is headquartered in Fort Worth, TX. We apologize for any confusion.